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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,658	01/24/2005	Hideki Murata	09859/0202424-USO	8728
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DARBY & DARBY P.C. P.O. BOX 770 Church Street Station New York, NY 10008-0770				
			EXAMINER FERNANDEZ, SUSAN EMILY	
			ART UNIT 1651	PAPER NUMBER
			MAIL DATE 05/18/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/522,658

Applicant(s)

MURATA ET AL.

Examiner

Susan E. Fernandez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

The amendment filed February 6, 2007, has been received and entered.

Claims 1-6 are pending and examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Specifically, claim 1 recites at step [1] that the methanol solution is added to a culture “...or a processed product of the culture and a partially purified product of ubiquinone-10 selected from...” (emphasis added), which constitutes as new matter. However, step [1] disclosed on page 3, lines 2-7 of the specification recites “adding a methanol solution to a culture..., a processed product of the culture, or a partially purified product of ubiquinone-10” (emphasis added). Clearly the specification does not teach simultaneously adding the methanol solution to both a processed product of the culture and a partially purified product of ubiquinone-10. Because the specification as filed fails to provide clear support for the new claim language, a new matter rejection is clearly proper.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 56-131394.

JP '394 discloses a method wherein 10 g of crude coenzyme Q₁₀ (which is another term for ubiquinone-10, see abstract of Frei et al, PNAS, 1990, 87: 4879-4883) produced by fermentation of *Protaminobacter ruber* (a bacteria), was dissolved in a solution which was furthered treated with 20 ml of a 28% NH₄OH-MeOH (ammonium hydroxide-methanol) (5:95) mixture at 10°C for 20 minutes. See the CAPLUS English abstract. The crude coenzyme Q₁₀ can be considered to be a processed product of a culture of ubiquinone-10-producing microorganism, or a partially purified product of ubiquinone-10. This step meets nearly all the

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requirements of step [1] of instant claim 1, except that it does not teach the volume of the methanol solution relative to the volume of product being treated as recited in instant claim 1. Next, after retaining the resulting mixture at 10°C for 20 minutes, the NH₄OH-MeOH layer is discarded, and this step meets the limitations of step [2] of instant claim 1. Then, the remaining impurities (insoluble matter) are extracted a second time with 20 mL of 95% MeOH solution at 10°C for 20 minutes. This step meets nearly all the limitations of step [3] of instant claim 1, except for the temperature at which the resulting mixture is retained. Next, a purified coenzyme Q₁₀ is recovered from this extraction, thus insoluble matter had to have been removed, thus step [4] of instant claim 1 is taught by the reference. Finally, the purified coenzyme Q₁₀ is crystallized from acetone.

As discussed above, the methods disclosed in JP '394 differ from the instant invention in that JP '394 does not teach the final concentration of 50 to 100 v/v% of methanol solution in the total volume of the resulting mixture, as recited in step [1] of instant claim 1. Nevertheless, the selection of a specific volumetric ratio of methanol solution to the total resulting mixture would have been a routine matter of optimization on the part of the artisan of ordinary skill in the art, said artisan recognizing that the extraction of impurities would have been dependent on the concentration of the methanol solution present in preparing the resulting mixture. Thus, limitations recited in step [1] of instant claim 1 are rendered obvious by the reference.

Additionally, as discussed above, the methods disclosed in JP '394 differ from the instant invention in that JP '394 does not teach the temperature at which the resulting mixture is retained after the insoluble matter is treated with methanol solution, as recited in step [3] of instant claim 1. Nevertheless, the selection of specific suitable temperatures for retaining the resulting

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mixture, including that claimed, clearly would have been an obvious matter of optimization on the part of the artisan of ordinary skill in the art. Thus, all limitations of step [3] of instant claim 1 are rendered obvious by the reference.

Therefore, JP '394 renders obvious instant claims 1 and 3. Given that a crystallized pure coenzyme Q₁₀ is taught by JP '394 as the final product of their method, instant claim 5 is also rendered obvious.

Additionally, at the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have repeatedly treated the insoluble matter with the 95% methanol solution following initial treatment of crude coenzyme Q₁₀ with a methanol solution, therefore rendering claim 2 obvious. One of ordinary skill in the art would have been motivated to repeat this step in order to have further purified the insoluble matter by extracting more of the impurities by performing extra extractions. Repetition of methanol treatment would have ensured maximal extraction and maximal removal of impurities. The repetition of process steps would have been prima facie obvious in the absence of new or unexpected results. Thus, claim 2 is rendered obvious by the reference.

Also, at the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have used any of the forms recited in claim 4 as the crude coenzyme Q₁₀ required for the practice of JP '394. One of ordinary skill in the art would have been motivated to do this since there would have been a reasonable expectation of success in successfully purifying coenzyme Q₁₀ with any of these forms. Moreover, one would have been motivated to have used these forms since these forms may be stored for long periods of time. Thus, claim 4 is rendered obvious by the reference.

Finally, it is noted that JP '394 does not expressly disclose adding a methanol solution to a partially purified product of ubiquinone-10 selected from the group consisting of ubiquinone-10-containing dried products, freeze dried products, and crystallized products. However, there would have been a reasonable expectation of success in successfully purifying ubiquinone-10 from a variety of ubiquinone-10-containing products with the methods disclosed in JP '394, as the extraction process would function in the same manner as long as ubiquinone-10 is present in the starting material.

A holding of obviousness is clearly required.

Response to Arguments

Applicant's arguments filed February 6, 2007, have been fully considered but they are not persuasive. With respect to the difference in the final concentration of the methanol solution of step [1], it is respectfully pointed out that, as mentioned above, the selection of a specific volumetric ratio of methanol solution to the resulting solution would have been a routine matter of optimization on the part of the artisan of ordinary skill in the art. Applicant asserts that JP '394 does not teach or suggest "an insoluble matter containing ubiquinone-10" as recited in claim 1. However, it is respectfully noted that the hexane layer containing ubiquinone-10 is indeed insoluble matter since impurities are present in the hexane layer containing ubiquinone-10 (abstract, "...remaining impurities extracted a 2nd time from the hexane...").

In addressing the differences between step [3] of JP '394 and step [3] of claim 1, applicant asserts that for claim 1, ubiquinone-10 in the resulting insoluble matter is extracted. However, it is respectfully noted that step [3] of claim 1 does not recite any extraction. Although

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the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Further still, as pointed out above, the selection of specific suitable temperatures for retaining the resulting mixture would have been an obvious matter of optimization on the part of the artisan of ordinary skill in the art.

Applicant asserts that JP '394 teaches that a purified ubiquinone-10 is recovered in a resulting hexane solution, whereas steps [4] and [5] of claim 1 require that a purified ubiquinone-10 is recovered in a resulting methanol solution. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., purified ubiquinone-10 recovered in a resulting methanol solution) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Instead, in the claims, after obtaining the resulting mixture of step [3], the insoluble matter is removed (as occurs with extraction by addition of a methanol solution as discussed in JP '394), and then a ubiquinone-10-containing solution is recovered.

In sum, as the claims do not recite extraction with hexane, and since the volume concentration and the temperature of the methanol solution may be altered by routine optimization, the claimed invention is indeed taught by JP '394. The rejections of record must be maintained.

No claims are allowed.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

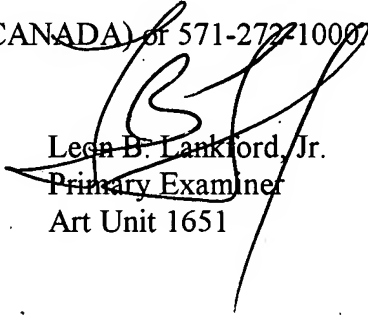
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan E. Fernandez whose telephone number is (571) 272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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